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EXAMINER

SMITH, RUTH S

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### ***Claim Objections***

Claims 25-29, 32-33 objected to because of the following informalities: The claims fail to positively set forth an active step in the method. Claims 25-27 set forth a further limitation regarding the type of contrast agent used but fail to set forth an active step in the method. Claims 28-29 set forth the type of image generated but fail to positively set forth an active step in the method. Claims 32-33 are merely directed to a use of the method and fail to set forth a further step in the method. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26,27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 26, 27, “the method of said blood pool MR contrast agent” lacks antecedent basis.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 24 is rejected under 35 U.S.C. 102(e) as being anticipated by Mistretta et al (6,381,486). Mistretta et al disclose a method of MRA which includes administering by injection a bolus of a blood pool MR contrast agent, generating a contrast enhanced MR image of a body part during the first pass of the contrast agent, generating at least one further MR image of the body part in a “steady state” portion of the exam when the

contrast agent has become substantially uniform. Mistretta et al disclose that it is known to image the kidney in examining the vasculature. It should be noted that the claim only sets forth a step of administering a contrast agent and generating two images. The recitation of "thereby allowing both visualization and gradation of renal artery stenosis and quantification of renal perfusion" is not considered to be a limiting step in the method but merely a possible use of the method steps.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24,32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al in view of Stark et al ( "Magnetic Resonance Imaging") and further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al. Mistretta et al disclose a method of MRA which includes administering by injection a bolus of a blood pool MR contrast agent, generating a contrast enhanced MR image of a body part during the first pass of the contrast agent, generating at least one further MR image of the body part in a "steady state" portion of the exam when the contrast agent has become substantially uniform. Mistretta et al disclose that it is known to image the kidney in examining the vasculature. Stark et al disclose using MRA to

examine the kidney to determine the presence of abnormalities such as renal stenosis. The MR data obtained by Stark et al is indicative of renal stenosis. Schurfeld et al disclose that “a higher grade renal artery stenosis causes a reduced arterial perfusion...” Lerman et al disclose on page 1462 that perfusion correlates significantly with severity of stenosis. Therefore, the MR data obtained by Stark et al which is “indicative” of renal stenosis grade is inherently also “indicative” of renal perfusion. It would have been obvious to one skilled in the art to have modified Mistretta et al such that the method is used to examine the kidney and to determine the presence or absence of any conditions which can cause known abnormalities such as renal artery stenosis grade, renal perfusion, intra-parenchymal blood volume and parenchymal damage. The modification merely involves using the known method of examining vasculature, as disclosed by Mistretta et al, on the kidney to provide a diagnosis of such an organ as taught by Stark et al. The modified method would allow one to quantify both renal stenosis and renal perfusion if so desired.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al alone or in view of Stark et al ( “Magnetic Resonance Imaging”) and further in view of Schurfeld et al ( “Renovascular hypertension-a factor of progression?”) or Lerman et al as applied to claim 24 above, and further in view of Berg et al. Berg et al disclose MRI where a blood pool contrast agent comprising a superparamagnetic contrast agent is used. The contrast agent can include the particles as set forth in claims 26,27. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that the contrast agent is the one disclosed by Berg et al. Such a modification merely involves the substitution of one known type of blood pool contrast agent for another.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al alone or in view of Stark et al ( “Magnetic Resonance Imaging”) and further in view of Schurfeld et al ( “Renovascular hypertension-a factor of progression?”) or Lerman et al as applied to claim 24 above, and further in view of Fischer. Fischer discloses the use of a T<sub>2</sub>\*- weighted image during a first pass of an MR contrast agent. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that

during the first pass of the contrast agent a  $T_2^*$ - weighted image is generated. Such a modification merely involves the substitution of one known type of image generated during the first pass of a contrast agent for another.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mistretta et al alone or in view of Stark et al ( "Magnetic Resonance Imaging") and further in view of Schurfeld et al ("Renovascular hypertension-a factor of progression?") or Lerman et al as applied to claim 24 above, and further in view of McMurray et al. McMurray et al disclose the use of a  $T_1$ - weighted image in combination with an MR contrast agent. The advantage of using a  $T_1$ - weighted image is well known in the art. It would have been obvious to one skilled in the art to have further modified Mistretta et al such that during the steady-state portion of the examination a  $T_1$ - weighted image is generated. Such a modification merely involves the substitution of one known type of image generated during a steady state portion of an MR contrast enhanced method for another.

### ***Response to Arguments***

Applicant's arguments filed January 19, 2010 have been fully considered but they are not persuasive. It should be noted that claim 24 does not set forth a method which includes providing quantified data for both renal perfusion and renal stenosis grade in a single examination. The claim steps merely **allow** visualization and gradation of renal artery stenosis and quantification of renal perfusion. This does not provide a method which positively includes providing quantified data for both renal perfusion and renal stenosis grade in a single examination. Furthermore, as previously stated, the Examiner does not agree with Applicant's remarks that none of the prior art documents are related to renal perfusion. Both Schurfeld et al ("Renovascular hypertension-a factor of progression?") and Lerman et al are cited as a teaching that renal stenosis is inherently indicative of renal perfusion. It should be further noted that the modified method of Mistretta would **allow** one to quantify both renal stenosis and renal perfusion if so desired.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737